

REMARKS

Status of the Claims

Claims 1-7, 9-13, 15-17, 19, 22, 25, 28 and 30-34, 35, and 35-54 were pending.¹

Claims 1-7, 9-13, 30-32, and 34-35, 35-54 stand allowed.

Claims 15, 17, 19, 22, 25, 28 and 33 stand rejected.

Claims 25, 28 and 33 are canceled herein.

Claims 1, 15, 19, 22, "35" (2nd), 42, and 43 are amended herein.

Claims 56-58 are new claims.

Reconsideration is respectfully requested.

Applicants gratefully acknowledge that the Examiner has found claims 1-7, 9-13, 30-32, and 34-54 to recite allowable subject matter. Claims 15-17, 19, 22, 25, 28 and 33 stand rejected. Claims 25, 28 and 33 are canceled herein, rendering the rejections to those claims moot. Claims 15, 17, 19, and 22 are amended (with claim 16 depending upon amended claim 15), and Claims 56-58 are new claims.

Below, Applicants first discuss the amendments to the allowed claims, then the amendments to the rejected claims, and then the new claims.

Allowed Claims 1-7, 9-13, 30-32, and 34-35, 35-54

With regard to the allowed claims, this amendment corrects minor matters of form.

Claim 1 was amended to delete the term "substituted heterocyclo" in the definition for R₆. The definition for "heterocyclo" appearing at page 6 of the specification recites that the term "heterocyclo" includes optionally-substituted heterocyclos, and thus, reciting "substituted heterocyclo" for R₆ was redundant.

Additionally, claim 1 was amended to introduce the word "about" before 24 hours in step c). Notably, each of the other temporal references in claim 1 is preceded by the word "about", and thus, this amendment is designed to enhance the consistency of language used in claim 1. A similar amendment is made to claim 42. Use of the word "about" in claims 1 and 42 is further supported in the specification at page 13, line 31.

It is submitted that these amendments relate only to form and do not change the scope of the claims.

¹ Two claims were numbered "35" which is corrected herein.

Claim "35" is amended only because the previous amendment had presented two claims 35, so this claim was renumbered to avoid confusion.

Rejected Claims 15-17, 19 and 22

Rejected claims 15, 17, 19 and 22 are amended herein. Applicants have amended these claims to recite a pharmaceutical preparation including the subject matter indicated by the Examiner as being allowable (*i.e.*, as specified at page 5 of the Office Action mailed on August 11, 2004).

In the Office Action, the Examiner had rejected claims 15-17, 19 and 22 as being not patentably distinct from claims 1-31 of commonly-assigned US Pat. 6,689,802. The '802 patent discloses crystalline polymorphs of compounds of formula I and/or II herein. The Examiner argued that, while the process claims were allowable, once the lyophilized material and/or the crystalline material is placed in solution, the material dissolves such that the same compound is present. Applicants need not address whether this argument possesses substantive merit because the instant claims are not directed to a solution of epothilone analogs, nor to a solution formed upon fully reconstituting lyophilized epothilone analogs. Rather, the instant claims are directed to processes for forming *lyophilized* epothilone analogs, to pharmaceutical preparations containing the *lyophilized* epothilone analogs in *lyophilized* form, and to methods of treatment that include use of *lyophilized* epothilone analogs. Thus, the claims are not directed toward a resulting solution that is formed upon full reconstitution of lyophilized epothilone analogs. That the lyophilized epothilone analogs *can be* fully reconstituted into a solution such that the lyophilized matter no longer appears does not change the scope of the claims to recite such a solution *per se*.

Applicants have amended claim 15 to underscore that the claim is directed to the lyophilized epothilone analog in lyophilized form, and additionally, to include the subject matter the Examiner had indicated was allowable, *i.e.*, the steps of dissolving an epothilone analog in a t-butanol and water solution, drying the solution under vacuum, and performing a secondary drying to obtain the lyophilized epothilone analog. (Office Action at p. 5).

Claim 15 was further amended, similar to claim 1, to delete the term "substituted heterocyclo" for R₆, because the definition of "heterocyclo" appearing at page 6 of the specification already recites that "heterocyclo" includes optionally-substituted heterocyclos, rendering "substituted heterocyclo" for R₆ redundant.

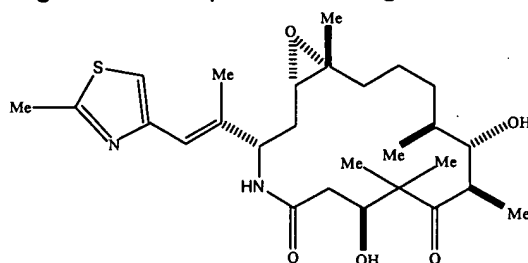
Claim 16 was not amended but it is dependent upon claim 15, and thus, should be allowable at least for the reasons specified above for claim 15.

Claim 17 was amended for antecedent basis purposes because, given the amendments to claim 15, the solvent or solvent mixture now first appears in claim 19.

Claims 19 and 22 were amended to clarify that the claims are directed toward a pharmaceutical preparation containing a lyophilized epothilone analog, as opposed to the resulting solution that may be formed upon fully reconstituting the lyophilized analog.

New Claims

New claims 56-58 are directed toward “a process of preparing an epothilone analogue comprising the steps of dissolving the analogue in a t-butanol water solution, drying the solution under vacuum and performing a secondary drying to obtain a lyophilized product.” This is a verbatim recitation of the subject matter indicated at page 5 of the Office Action as being allowable. Further, Applicants have included in these claims that the particular epothilone analog is the compound having the formula,



Information Disclosure Statement

Applicants also bring to the Examiner's attention that an Information Disclosure Statement is submitted herewith which includes patents commonly-assigned to the present assignee. Also included on the IDS are references cited by the Examiner during the prosecution of patent applications leading to US Pat. Nos. 6,576,651 and 6,670,384, assigned to the present assignee.

Fees

An RCE and petition for one-month extension of time is submitted herewith, with fees paid for same. It is not believed that any additional fees are due. Although three claims are added, three claims have been canceled. However, if it is determined that an

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additional fee is due, the Commissioner is authorized to charge same to Deposit Account No. 19-3880 in the name of Bristol-Myers Squibb Company.

SUMMARY

It is believed that the above amendments place the entire application in condition for issuance. The Examiner is invited to contact the undersigned if it is believed a telephonic communication would expedite the prosecution of this application.

Respectfully submitted,



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